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J. Am. Coll. Cardiol. Intv. 2012;5;229-235; originally published online Feb 8, 2012; doi:10.1016/j.jcin.2011.12.004

JACC: CARDIOVASCULAR INTERVENTIONS
VOL. 5, NO. 2, 2012

ISSN 1936-8798/$36.00
PUBLISHED BY ELSEVIER INC.
DOI: 10.1016/j.jcin.2011.12.004

EXPEDITED PUBLICATIONS: VIEWPOINT

Percutaneous Coronary Intervention Use in the United States

Defining Measures of Appropriateness

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Appropriate utilization of percutaneous coronary intervention (PCI) and medical therapy is deservedly a national healthcare policy priority for the United States. Because PCI is both common and costly, appraisal of appropriateness is warranted. The initial appropriate use criteria (AUC) have been developed for coronary revascularization procedures and investigators recently reported the appropriateness for the approximately 500,000 PCI procedures performed at centers participating in the National Cardiovascular Data Registry. The AUC have broad implications for both healthcare providers and our patients and will be used as the basis for indications, referral patterns, treatment options, physician education, shared decision-making, and reimbursement for years to come. While we acknowledge the importance of thoughtfully assessing appropriateness for all medical procedures including PCI, there are a number of concerns with the current AUC and methods used to report appropriateness that warrant expanded commentary. (J Am Coll Cardiol Intv 2012;5:229–35) © 2012 by the American College of Cardiology Foundation

Appropriate use of percutaneous coronary intervention (PCI) and medical therapy is deservedly a national healthcare policy priority. Because PCI is both common (1,2) and costly, appraisal of PCI use is warranted. Thus, when a recent appropriateness use paper was published in the *Journal of the American Medical Association* (JAMA), it received national attention and brought again to the forefront the possibility of PCI overuse in the United States (3). Following this publication, there was a flurry of national stories focusing on the apparent overuse of PCI (4,5). Often, these national stories link the *JAMA* paper findings to selected high-profile cases

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where individual operators are under legal investigation for the systematic overuse of PCI (6). As practicing clinical cardiologists, we all must remain committed to delivering high-quality and responsive care to our patients. Clinicians should also strive to offer treatments that minimize the burden of managing a chronic medical condition such as coronary artery disease, whether the burden stems from procedures, office visits, or medical therapy.

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Manuscript received December 2, 2011; accepted December 14, 2011.

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FEBRUARY 2012:229–35

The AUC Criteria

The appropriate use criteria (AUC) (7) have far-reaching implications for the delivery of cardiovascular care for our deserving patients and for the healthcare providers committed to serving their needs. As stated in the coronary revascularization AUC statement, these AUC will be used as the basis for indications, referral patterns, treatment options, physician education, and shared decision making for years to come. It is also stated that payers should use these criteria for the development of "a rational payment management strategy," such that members would receive effective, safe, and cost-efficient care.

The AUC authors also acknowledge several limitations inherent in any attempt to codify clinical decision making. They state that "these criteria provide a framework for discussion and are intended to assist patients and clinicians, but are not to diminish the difficulty or uncertainty of clinical decision making." The authors foreshadow that "many patients in clinical practice may not be represented in these initial AUC," and that "ranking of an indication as uncertain should not be viewed as excluding the use of revascularization for such patients." Last, that "it is not anticipated that all physicians or facilities will have 100% of their revascularization procedures deemed appropriate."

The interventional cardiology community must engage in this national discussion to better formulate a strategy of minimizing overuse and eradicating the systematic underuse of effective therapies in the United States. Our failure to adequately do so has left a large void in this debate.

Abbreviations and Acronyms

A = appropriate
ACC = American College of Cardiology
AUC = appropriate use criteria
CCS = Canadian Cardiovascular Society
CTO = chronic total occlusion(s)
FFR = fractional flow reserve
I = inappropriate
JAMA = *Journal of the American Medical Association*
LAD = left anterior descending artery
LV = left ventricular
PCI = percutaneous coronary intervention
RCA = right coronary artery
U = uncertain

The AUC Paper

A number of investigators have systematically evaluated the geographic variability of cardiac catheterization and PCI in the United States (8–12). Many reference this 2- to 3-fold variability in the use of PCI as evidence for both over- and underuse. In a similar fashion, Chan et al. (3) attempt to describe the appropriateness of PCI in a broad array of PCI indications at participating NCDR (National Cardiovascular Disease Registry) CathPCI centers. Although this is a noble effort, there are a number of concerns that warrant expanded commentary.

Misinterpretation of the data. The objective of the Chan et al. (3) paper was to "assess the appropriateness of PCI in the United States." Unfortunately, the overall appropriateness rate was not presented in the original publication. Rather the investigators presented the inappropriate rate for acute and nonacute indications separately. For acute PCI, the majority of indications (98.6%) were mapped as appropriate, whereas for nonacute PCI, appropriate indications were found in only one-half (50.4%) of the sample. In light of the stated objective of this paper, we believe the editors of the *JAMA* and the investigators should have presented the data in a more objective, less "sensational" manner. For the entire population, the appropriate (A), uncertain (U), and inappropriate (I) rates for the 500,000 PCI procedures in the *JAMA* paper were 84.6%, 11.2%, and 4.1%, respectively. To present stratified data without providing the overall inappropriate rate is misleading. As an illustration, one could not imagine the original BARI (Bypass Angioplasty Revascularization Investigation) trial manuscript presenting only the treated diabetic subgroup without including a detailed analysis from the overall trial findings (13). Chan et al. (3) also point to a wide variation in inappropriate PCI as evidence of a culture of poor patient selection in some centers. They report hospitals in the lowest quartile had inappropriate rates of 6% or lower versus 16% or higher for the highest quartile hospitals. However, this refers only to nonacute PCIs (28.9% of the entire study group). If we extrapolate this rate of variation to the entire study group, the statement would read: Hospitals in the lowest quartile had inappropriate PCI rates of 1.73% or lower versus 4.62% or higher for the highest quartile hospitals.

Nevertheless, inappropriate use was identified, which begs the questions: Is it reasonable to expect a "zero tolerance" for inappropriate PCI rates on a national basis? And if there is a tolerable rate of inappropriate PCI, what is an "acceptable threshold"? Given the current imprecise methods used to develop the AUC, a zero frequency is neither expected nor realistic. There remains too much uncertainty around the mapping of complex clinical scenarios when assigning A, U, or I. This fact is acknowledged by the AUC Writing Committee in the original manuscript. Recognizing and putting into context the upper threshold is difficult. For example, the 1.1% inappropriate rate for the acute PCI indications might be lower than expected. One might reasonably infer from this rate evidence for systematic underutilization for the acute indications, as has been suggested by other data (9). A stated goal of the AUC committee includes using A, U, or I in quality reporting. It has been suggested that "national norms" will serve as the threshold. If that is the case, the AUC committee and NCDR need to understand in detail, the many factors that contribute to hospital variability.

Limitations of the AUC

Lack of concordance between AUC technical panel and clinical cardiology community. The AUC committee purposefully limited involvement of the interventional community during the development process. The AUC guidelines were devised by a "technical panel created so as to not include a majority of individuals whose livelihood is tied to the technology under study." To prevent bias, "the panel was deliberately comprised of physicians with varying perspectives on coronary revascularization and not comprised solely of experts in the procedure undergoing evaluation." Of the 17 members, only 4 were content experts for PCI indications. The panel included 4 interventional cardiologists, 4 cardiovascular surgeons, 8 members representing cardiologists and other medical doctors who treat patients with cardiovascular disease or health outcome researchers, and 1 health plan medical officer. The motivation for excluding interventional cardiologists was to prevent financial and/or intellectual bias from unduly influencing the process. Assessing bias at the individual level, whether financial or intellectual, is challenging. However, assigning bias for every individual within a medical subspecialty seems overly judgmental. Clearly, there are U.S. interventional cardiologists who practice in an environment where remuneration is not in any way linked to PCI volume. (S.P.M. and J.A.G. currently practice in such an environment.) There are also countless excellent international interventional cardiologists who are both content experts and in no way have a financial interest in U.S. PCI AUC. Additionally, many argue the presence of intellectual bias to dismiss individuals (not entire subspecialities) from participation in committee meetings. Although there are no statutory or regulatory criteria to define intellectual bias, and it can be difficult to identify and/or quantify (14,15), the U.S. Food and Drug Administration has a vested interest in attempting to minimize the possibility of intellectual bias among panel members. Thus, their approach to minimizing intellectual bias is germane. The current thinking about intellectual bias at the agency has been revisited recently because of 2 high-profile cases (14). Intellectual bias is believed to exist when a group member is identified as a strong advocate for an ideal and a reasonable person would doubt whether he or she could impartially or objectively offer an opinion. The Food and Drug Administration evaluates intellectual bias within individuals. It does not assign intellectual bias to an entire medical subspecialty.

Limiting the technical panel likely affected the outcome. There was strong disagreement when the AUC technical panel rankings were compared with clinical cardiologists' rankings. Eighty-five cardiologists from 10 U.S. institutions assessed the appropriateness of coronary revascularization for 68 indications that had been created by the AUC Technical Panel (16). This study found excellent concordance (94%) between the AUC Technical Panel and the larger physician group for appropriate indications. There was only modest concordance (70%) for inappropriate indications. Additionally, there was wide variation (i.e., nonagreement) in ratings of appropriateness among the physician group, with more than 25% of physicians assigning an appropriateness category different from the group as a whole in 2 of every 3 scenarios. This variability was substantial when correlating individual physicians and the AUC Technical Panel for inappropriate or uncertain indications. Moreover, there was substantial variation in appropriateness category assignments between individual physicians and the AUC Technical Panel, with some physicians almost never agreeing with the AUC Technical Panel and "no physician achieving more than 80% agreement."

The lack of concordance for the appropriate use scenario 12B was notable and this scenario was the most common reason for a PCI to be categorized as inappropriate, accounting for 39.6% of all such cases among nonacute patients. Scenario 12B is described as patients with 1- to 2-vessel disease, no proximal left anterior descending artery (LAD) involvement or prior coronary artery bypass graft, class I or II symptoms, low-risk noninvasive findings, and on no or minimal medications. The median score was uncertain for the physician group, whereas it was categorized as inappropriate by the technical panel. Chan et al. (3) argue that the AUC panel serve as the "gold standard" and that there exists a re-education opportunity for dissenting physicians. An equally plausible argument is that the AUC Technical Panel, including the 4 interventional cardiologists, got this one wrong.

Lack of specific criteria for interpreting pre-procedural stress testing. The vast majority of AUC scenarios require knowledge of pre-procedural stress test findings. However, there are a number of problems regarding the validity and reliability of assigning a low, intermediate, or high risk to pre-procedural stress testing. The NCDR does not require interpreting physicians to determine this risk. Therefore, this data collection burden falls onto the data abstractors, who are required to assign a risk category based on vague guidelines. Essentially, they are required to interpret the interpretation. Various modalities including exercise electrocardiogram, stress echocardiograms, stress single-photon emission computed tomography, and contrast enhanced magnetic resonance imaging are accepted by the NCDR (positron emission tomography was not included in the pre-procedural stress testing options). Abstractors are required to code the test as negative, positive, or indeterminate; if it is positive, abstractors are to assign risk (low, intermediate, high, or indeterminate). Unfortunately, the AUC criteria to determine risk, including high risk, are surprisingly nonspecific. The current recommendations for categorizing a stress test as high risk are shown in Table 1. Among others, a "large stressed induced perfusion defect

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Table 1. High-Risk Nuclear Stress Test Findings According to the AUC Writing Committee

Resting LVEF <35%
High-risk treadmill score (≤11)
Severe exercise LVEF <35%
Stress-induced large perfusion defect
Stress-induced multiple perfusion defects
Large, fixed perfusion defect with LV dilation or increased lung uptake
LV dilation or increased lung uptake
Stress-induced moderate perfusion defect with LV dilation or increased lung uptake

AUC = appropriate use criteria; LV = left ventricular; LVEF = left ventricular ejection fraction.

particularly if anterior" for single-photon emission computed tomography classifies a study as high risk. Neither the American College of Cardiology (ACC)/NCDR CathPCI data definitions nor the AUC further define "large perfusion defect" (17). Likewise, no reference to a definition for moderate or small defect is provided. There is also no guidance as to the preferred method for how to quantify the perfusion defect (sum difference score or polar map methodology) and no statement about how to use the intensity of ischemia in the determination of risk. This same lack of specificity exists for other modalities including stress echocardiography. There is also a clerical error in the NCDR handbook for coders describing a high-risk contrast magnetic resonance imaging as a "a large, fixed perfusion defect with LV dilation or increased lung uptake (thallium-201) and/or a stress-induced moderate perfusion defect with LV dilation or increased lung uptake (thallium-201)."

Although it is clear that stress electrocardiogram criteria can also inform risk (using the Duke treadmill score), the instructions for the data abstractors do not explicitly guide them as to when the high-risk electrocardiogram component of a stress test should supplant a normal or mildly abnormal imaging portion. Furthermore, it is not clear how the abstractors should deal with a presumably false negative pre-procedural stress test when the coronary angiogram clearly demonstrates high-risk anatomy and/or fractional flow reserve (FFR) demonstrates a functionally significant stenosis confirming the false negative stress test interpretation. This lack of clarity and specificity in assigning high risk will lead to considerable hospital variation when documenting stress test risk in the NCDR data case report forms. It would be interesting to know the degree to which physicians participated in the ultimate risk assessment that was entered into the NCDR case report form as opposed to abstractors getting feedback from the NCDR help line. Because the appropriateness categories are inexorably linked to the presence or absence of intermediate/high-risk stress findings, much of the center level variability in appropriateness may be related to interpretation of stress test findings. Future AUC criteria should specifically quantify the area of ischemia and infarction associated with low-, intermediate-, and high-risk scans. They should comment on intensity of ischemia. Moreover, the ACC should encourage centers to clearly summarize this information in stress testing final reports. The ACC should then increase the emphasis on center-level education about documenting stress test risk and then perform repeatability validation studies on a subset of these results. Last, centers should develop center-level standard operating procedures to clearly report and collect key stress test findings such that appropriateness can be reliably categorized based on stress test findings.

Inability to link stress test results to coronary anatomy. There is no mechanism for linking the noninvasive test abnormality to the angiogram. Consider the case of a patient with class II angina on 1 antianginal drug with moderate risk right coronary artery (RCA) distribution ischemia found to have a chronic total occlusion (CTO) of the RCA and a 70% hemodynamically insignificant lesion in the proximal LAD. PCI of the proximal LAD lesion would be categorized as appropriate, whereas a PCI of the RCA CTO would be inappropriate. Future AUC ought to develop a strategy to correctly identify whether the culprit lesion was treated during the percutaneous revascularization procedure. This could be done by coupling stress test findings with the target vessel intervention.

Inability to assess appropriateness in stable patients without pre-procedural stress testing. Though it is often appropriate to perform stress testing in symptomatic patients to either estimate the likelihood of coronary artery disease, localize ischemia, and/or to risk stratify patients before coronary angiography, it is not medically necessary to do so. According to the Baye theorem, stress testing (for the sole purpose of identifying coronary artery disease) is not useful in patients at very high or very low pre-test probability for coronary artery disease. In fact, doing so is not only unreliable but adds expense. Even though the AUC committee acknowledges this, there is an overdependence on performing pre-procedural stress testing for nonacute PCI indications. For example, an individual on 1 antianginal medication with Canadian Cardiovascular Society (CCS) class III angina found to have a 90% lesion in the proximal left circumflex was not mapped to A, U, or I in the absence of stress testing or FFR. This mapping algorithm requires improvement. There should also be a greater emphasis on performing FFR of angiographic indeterminate lesions. The FAME (Fractional flow reserve versus Angiography for Multivessel Evaluation) trial has informed the medical community that the probability of an adverse cardiovascular event is extremely low if FFR is negative (>0.80) (18). We believe this predictive ability is at least as good as (and likely superior to) the predictive capabilities of noninvasive testing. We firmly believe that pre-procedural stress testing is not requisite before coronary angiography in all symptomatic patients.

Angiographic determinants of appropriateness (proximal LAD and CTO lesions). Very few angiographic variables were used to assess appropriateness and included only involvement of the left main, proximal LAD and multivessel disease. The AUC identifies the proximal LAD as a special region of interest. If PCI was performed in the proximal LAD, there were no occasions where PCI was inappropriate for the nonacute indications, as long as patients had not undergone prior bypass surgery. In these cases, no attempt was made to assess whether a graft was patent or occluded. Of the 17,000 inappropriate nonacute PCI cases, 6% were procedures involving PCI to the proximal LAD among patients with prior bypass surgery. Future AUC should align the proximal LAD mapping for patients with and without prior bypass surgery by collecting graft status.

Both the AUC Technical Panel and the larger physician group found scenario 14A inappropriate, yet scenarios 30A and 36A uncertain. These three scenarios are nearly identical (1- to 2-vessel disease, no prior coronary artery bypass graft, class I or II symptoms, intermediate risk from noninvasive findings, patient on no or minimal medications). Scenario 14 involves the proximal LAD, whereas scenarios 30 and 36 do not. Although a superficial understanding of coronary revascularization trials and coronary anatomy seems to justify this distinction, in practice, coronary anatomy is more complex. In most cases, the proximal LAD supplies 50% or more of the myocardium, but there are numerous situations in which vessels other than the proximal LAD take on equal or more importance as evidenced by the importance of ischemic burden on outcomes (19–21). For example, a patient with high-grade proximal stenosis in a large, dominant circumflex artery, or a patient with an occluded LAD but disease in a large RCA and/or circumflex would be extremely dependent on a non-LAD PCI target.

The only complex lesion subset addressed in the current AUC is CTO. The rationale for this is unclear. There are a number of complex lesions that require specific technical approaches to successfully complete the procedure. Specific examples include vessels with excessive tortuosity, bifurcation lesions, calcification, ostial lesions, and diffuse disease. We think incorporating these lesion subsets including CTO-PCI is beyond the scope of AUC and creates inconsistencies. CTOs are commonly found at the time of coronary angiography and account for 5% to 10% of total PCIs performed in the United States (22). The expected benefits of CTO-PCI include symptom relief (23), improved LV function (24), avoidance of other procedures and possibly improved survival (25,26). Only single-vessel CTOs are specifically addressed in the AUC. In comparing single-vessel CTO AUC to 1- or 2-vessel disease not involving the proximal LAD, there are 5 "downgrades" for appropriateness of CTO. However, in the presence of multivessel disease, specific AUC "was not included as a separate indication since other variations of multivessel disease are present." This leads to a paradox when attempting to incorporate CTO-PCI AUC into clinical practice. In the setting of multivessel disease, there are no "down classifications" in appropriateness for CTO revascularization. However, if the CTO-PCI is staged after the non-CTO lesion, its appropriateness designation changes.

CCS class II angina. The AUC generally assigns an inappropriate status to CCS class II patients without an attempt at improving symptoms with antianginal medications. This assignment implies that either PCI is ineffective relative to medical therapy or that the AUC investigators believe that medical therapy is preferable to PCI by requiring "preauthorization" before undergoing PCI. The explicit goals of therapy for managing chronic angina are to prevent major cardiovascular complications and to relieve symptoms (27,28). Both the COURAGE (Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation) (29) and BARI 2D (Bypass Angioplasty Revascularization Investigation 2 Diabetes) trials (27,30) demonstrate that PCI improves anginal symptoms in patients with chronic stable angina. In the latter trial, Dagenais et al. (30) demonstrate that initial coronary revascularization was superior to medical therapy in maintaining freedom from angina, preventing new onset angina, and arresting worsening angina in type 2 diabetic patients during 3 years of follow-up. Differences between the revascularization and medical therapy groups were striking during the first year following randomization but diminished over time as the medical therapy improved their CCS classification. Frequently, individuals argue that PCI is costly relative to chronic medical therapy for the relief of anginal symptoms. However, in a BARI 2D report, the lifetime costs of medical therapy were slightly higher (31). If shared medical decision making is a valued informed consent process, physicians ought to have the opportunity to discuss both PCI and medical therapy with CCS class II patients as being both effective and viable treatment options. We propose that CCS class II patients have significant angina, which is effectively managed with PCI. Future AUC should separate CCS class II from class I and acknowledge this in future revisions.

Validation of NCDR data collection. Many AUC-specific data elements were just recently incorporated into the NCDR version 4.0 data forms. These data are entirely self-reported and this effort is unfunded. In contradistinction to current standards for clinical research, there is minimal monitoring. Most institutions employ approximately 1 full-time employee per 1,000 PCIs to address this process, which is less than one-tenth of the full-time employee ratio employed for most clinical studies. Furthermore, the data entry fields are usually completed by catheterization laboratory technologists, nurses, or cardiology fellows. These individuals have varying expertise, skills, and interest. Finally, the data can be subject to "gaming," wherein symptoms are subtly over- or underreported, lesion stenoses overestimated and medications

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Table 2. Recommendations for PCI AUC Revisions

Minimizing overuse and underuse of PCI should be a national healthcare priority.
The AUC do not assess effectiveness (PCI can be appropriate without improvement of symptoms).
Scenario 12B (1- or 2-vessel disease, without proximal LAD, low-risk findings on noninvasive testing, 0 or 1 antianginal meds CCS class I or II) should be changed to uncertain.
The CTO-specific AUC categories should be removed.
Future AUC should:
Increase the number of clinical scenarios to decrease the unmappable rate (37% of all stable PCI cases were not mappable).
Re-evaluate the need to require a stress test in patients with symptomatic coronary artery disease.
Adopt an intelligent, data-driven strategy to incorporate FFR for culprit lesion identification.
The ACC should:
Recommit to educating sites regarding AUC-specific criteria.
Include bypass graft status
Develop alternative anatomic scenarios that approximate the amount of myocardium subtended by the proximal LAD.
Separate CCS class I and II and refrain from requiring pre-procedural stress testing in CCS class II.
A greater number of interventional cardiologists need to engage in the AUC process and to develop complementary methods to assess appropriateness.
Center-specific recommendations:
Develop an institutional peer review process to evaluate PCI categorized as inappropriate.
Draft standard operating procedures to capture stress test results including abnormal, normal, indeterminate, and if abnormal, low, intermediate, or high risk.
Develop standard operating procedures to specifically record patients' reporting of anginal symptoms

ACC = American College of Cardiology; AUC = appropriate use criteria; CCS = Canadian Cardiovascular Society; CTO = chronic total occlusion; FFR = fractional flow reserve; LAD = left anterior descending artery; PCI = percutaneous coronary intervention.

added only to "upgrade" patient status. The authors of the *JAMA* paper argue that by performing their analysis before making the effort known to interventional cardiologists, they have likely prevented any gaming of the data. However, the unintended consequence of this strategy was that many NCDR centers were not fully prepared to reliably collect CCS and stress test findings, which undoubtedly led to substantial misclassification.

Evidence for misclassification surfaced during the validation of the computer algorithm designed to automap PCI scenarios to A, U, or I. The *JAMA* investigators and NCDR requested that 11 institutions manually map 127 inappropriate procedures. Although they found 100% concordance with the automated mapping algorithm, there was evidence that the original source data collected by the institutions was inaccurate. During the process, it was discovered that 9 cases did not accurately represent an individual's angina status and/or noninvasive risk assessment (S.P.M., J.A.G. personal communication with Paul S. Chan, October 2011). We believe this should have prompted further evaluation of these newly launched AUC-specific data elements. The investigators chose to ignore this signal and press on with the project and publication plans. Misclassification also occurred at the primary institution for the first and senior authors of this viewpoint (S.P.M., J.A.G.), which is the same institution as the first and senior authors of the AUC *JAMA* publication (P.S.C., J.A.S.). We found 56% of all I cases were misclassified due to incorrectly coding CCS class status, not documenting angina equivalents, or inaccurate documentation of the noninvasive risk assessment findings. We believe the ACC/NCDR should recommit to educating participating NCDR sites on the appropriate collection of AUC-specific data elements. Until then, it could be argued that the CathPCI Research and Publications Committee should refrain from approving AUC-related clinical studies until such time that assurances are given that these data are both valid and reliably collected.

In summary, we applaud the work done to date assessing PCI appropriateness in the United States, but we recognize that much work remains. Table 2 provides a summary of high-priority items that should be addressed in the ongoing AUC revisions. Lastly, we encourage our interventional colleagues to identify additional methods to assess appropriateness and to engage in this national discussion to enhance the applicability, credibility, and sustainability of future AUC research. Looking forward, we believe there is a pressing need to recreate a more comprehensive, measurable PCI AUC.

Acknowledgments

The authors would like to thank Sandy Brennan and Josh Murphy for editorial assistance in the preparation of this manuscript.

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Key Words: appropriateness ■ percutaneous coronary intervention ■ public reporting ■ quality.

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J. Am. Coll. Cardiol. Intv. 2012;5;229-235; originally published online Feb 8, 2012; doi:10.1016/j.jcin.2011.12.004